

APPENDIX 5: PERSISTANT PIGMENT DARKENING: STUDY RESULTS

PPD DATA SUMMARY FROM CPTC



EST. 1975

Consumer Product Testing Co.

FINAL REPORT

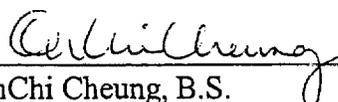
CLIENT: CTFA SPF Task Force
Round Robin Testing
1101 17th Street, N.W.
Washington DC 20036

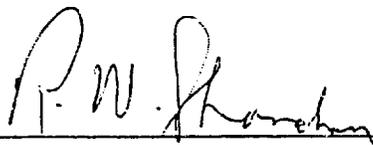
ATTENTION: Gerald McEwen, Jr., Ph.D., J.D.
Vice President – Science

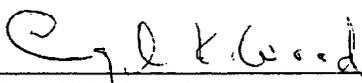
TEST: Sunscreen PFA Testing (PPD)
(JCIA recommended Persistent Pigment Darkening Method)
Protocol: 7.06

TEST MATERIALS: .01) Product A
.02) CTFA Sunscreen Sample E
.03) CTFA Sunscreen Sample F
.04) CTFA Sunscreen Sample G
.05) CTFA Sunscreen Sample H
.06) CTFA Sunscreen Sample I
.07) CTFA Sunscreen Sample J

**EXPERIMENT
REFERENCE NUMBER:** S00-0258


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EST. 1975

Consumer Product Testing Co.

QUALITY ASSURANCE UNIT STATEMENT

Study No.: S00-0258

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and reporting of clinical laboratory studies. The QAU maintains copies of study protocols and standard operating procedures and has inspected this study on the date(s) listed below. Studies lasting six months or more are inspected at time intervals to assure the integrity of the study. The findings of such inspections are reported to management and the Study Director. All materials and data pertinent to this study will be stored or disposed of in accordance with current Standard Operating Procedures.

Date(s) of inspection:

- March 17, 2000
- March 20, 2000
- March 22, 2000
- March 23, 2000
- April 1, 2000
- April 12, 2000
- April 17, 2000

Senior personnel involved:

Caryl K. Wood	-	Director of Photobiology
Robert W. Shanahan, Ph.D.	-	Vice President, Technology
Michael Lutz, B.S.	-	Technical Supervisor of Photobiology
Kathleen Alworth, B.A.	-	Director of Quality Assurance
Laura Artiles, M.A.	-	Supervisor, Administrative Services, Photobiology

The representative signature of the Quality Assurance Unit on the front page signifies that this study has been performed in accordance with standard operating procedures and study protocol as well as government regulations regarding such procedures and protocols as outlined in the Federal Register (Vol. 46, No. 17 of Tuesday, January 27, 1981).

Objective: To determine (in-vivo) the level of protection afforded by seven (7) sunscreen products against UVA radiation using Persistent Pigment Darkening (PPD) as a visual end point.

Test Samples:

.01) Product A	(expected PFA = 2-4)
.02) CTFA Sunscreen Sample E	(expected PFA = 1-3)
.03) CTFA Sunscreen Sample F	(expected PFA = 2-4)
.04) CTFA Sunscreen Sample G	(expected PFA = 3-5)
.05) CTFA Sunscreen Sample H	(expected PFA = 3-5)
.06) CTFA Sunscreen Sample I	(expected PFA = 1-3)
.07) CTFA Sunscreen Sample J	(expected PFA = 9-11)

Control Sample: A control standard formulated to provide an approximate Protection Factor of UVA (PFA) of 3.75 was run concurrently with the test material.

Study Schedule:

<u>Initiation Date</u>	<u>Completion Date</u>
March 13, 2000	April 10, 2000

Reference: The test procedure was based on the Japanese Cosmetic Industry Association (JCIA) recommended method for UVA Protection, based on Persistent Pigment Darkening.

Inclusion Criteria: Healthy male or female volunteers:

- a) 18 to 60 years of age;
- b) With Skin Types II - IV, determined by the following guidelines:

<u>Skin Type</u>	<u>Sunburn and Tanning History</u>
I	Always burns easily; never tans (sensitive)
II	Always burns easily; tans minimally (sensitive)
III	Burns moderately; tans gradually (normal)
IV	Burns minimally; always tans well (normal)
V	Rarely burns; tans profusely (insensitive)
VI	Never burns; deeply pigmented (insensitive)

**Inclusion Criteria
(continued):**

- c) Considered dependable and capable of following directions;
- d) Having completed a Medical History Form;
- e) Having read, understood and signed an Informed Consent Form.

Exclusion Criteria:

- a) Subjects with a history of abnormal response to sunlight;
- b) Subjects exhibiting current sunburn, suntan or uneven skin tone which might be confused with a reaction from the test material or interfere with the evaluation of test results;
- c) Pregnant or lactating females;
- d) Subjects taking medication which might produce an abnormal response to sunlight or interfere with the results of the test;
- e) Subjects who regularly use UVA Tanning beds; or
- f) Subjects exhibiting any visible skin disease which could be considered to affect the purpose or integrity of the study.

Test Method:

A total of thirty-two (32) subjects who met the inclusion criteria were selected for participation. Eleven (11) subjects tested samples .01 - .06 and ten (10) subjects tested sample .07.

Light Source: A Xenon Arc Multiport Solar Simulator* (150w) was used as the source of ultraviolet light. A continuous emission spectrum in the UVA range (320-400 nanometers), using Schott WG 335/2 mm and UG11/1 mm filters, was produced during the testing procedure by this instrument.

Determination of Minimal Persistent Pigment Dose (MPPD): The MPPD is defined as the time interval or dosage of UVA light exposure sufficient to produce a minimal, perceptible darkening on designated test sites. Prior to the testing phase, the MPPD of the unprotected skin of each subject was determined by a progressive sequence of timed UVA light exposures, graduated incrementally by 25% over that of the previous exposure. Persistent Pigment Darkening (PPD) values were determined by visual examination of the sites made 120 min., 180 min., and 240 min. after irradiation using the following scoring system:

**Test Method
(continued):**

- 0 = Negative, no visible pigment darkening
- 0.5 = Minimal pigment darkening
- 1.0 = Defined pigment darkening
- 2.0 = Moderate pigment darkening

Determination of PFA: A sufficient number of 5 x 7 cm test site areas were outlined with a surgical marking pen on the subject's back between the scapulae and the beltline, lateral to the midline. These areas were designated for the Test Material and Standard, with an adjacent site designated for a concurrent MPPD determination (unprotected control). The test and control material(s) were applied using a randomization scheme supplied by Consumer Product Testing Co.

A 2mg/cm² portion of the Test Material and of the Standard was applied to the appropriate designated test site and spread evenly over the site using a fingertip. After product application, the test areas were divided into five (5) sub-sites which were used for serial UVA light exposures. Irradiation of the sites was begun no less than 15 minutes and no longer than 30 minutes after application.

Exposure times were selected for each sub-site based upon the previously determined MPPD of the **unprotected** skin and the expected PFA of the Test Article or the Standard.

All test sites were evaluated at 120, 180 and 240 minutes post-irradiation to determine Minimal Persistent Pigment Darkening.

Calculation of the PFA - The PFA for the Test Material and Standard was calculated as follows:

$$\text{PFA} = \frac{\text{MPPD Test Material or Standard}}{\text{MPPD Unprotected Skin}}$$

**Sunscreen Category:
(Japan)**

For labeling purposes, a UVA sunscreen protection product may be categorized as follows:

<u>PFA Value</u>	<u>PA (Protection grade of UVA)</u>
2 or more but less than 4	PA+
4 or more but less than 8	PA++
8 or more	PA+++

**Test Results:
(Japan)**

PFA calculations for each subject are represented in Tables 1-7.

Product A

Results are based on eleven (11) subjects. Under the test conditions described, Test Material: Product A, exhibited an average PFA value of 3.24 at 120 minutes, 3.16 at 180 minutes, and >3.16 at 240 minutes and may be categorized as a PA+ UVA protective sunscreen product.

CTFA Sunscreen Sample E

Results are based on eleven (11) subjects. Under the test conditions described, Test Material: CTFA Sunscreen Sample E, exhibited an average PFA value of 1.72 at 120 minutes, 1.60 at 180 minutes, and 1.64 at 240 minutes.

CTFA Sunscreen Sample F

Results are based on eleven (11) subjects. Under the test conditions described, Test Material: CTFA Sunscreen Sample F, exhibited an average PFA value of 3.23 at 120 minutes, 3.06 at 180 minutes, and 3.06 at 240 minutes and may be categorized as a PA+ UVA protective sunscreen product.

CTFA Sunscreen Sample G

Results are based on ten (10) subjects. Under the test conditions described, Test Material: CTFA Sunscreen Sample G, exhibited an average PFA value of 3.88 at 120 minutes, 3.78 at 180 minutes, and 3.86 at 240 minutes and may be categorized as a PA+ UVA protective sunscreen product.

CTFA Sunscreen Sample H

Results are based on ten (10) subjects. Under the test conditions described, Test Material: CTFA Sunscreen Sample H, exhibited an average PFA value of 3.98 at 120 minutes, 4.35 at 180 minutes, and 4.43 at 240 minutes and may be categorized as a PA++ UVA protective sunscreen product.

CTFA Sunscreen Sample I

Results are based on ten (10) subjects. Under the test conditions described, Test Material: CTFA Sunscreen Sample I, exhibited an average PFA value of 2.27 at 120 minutes, 2.27 at 180 minutes, and 2.31 at 240 minutes and may be categorized as a PA+ UVA protective sunscreen product.

**Test Results
(continued):**

CTFA Sunscreen Sample J

Results are based on ten (10) subjects. Under the test conditions described, Test Material: CTFA Sunscreen Sample J, exhibited an average PFA value of 10.80 at 120 minutes, 10.80 at 180 minutes, and 10.57 at 240 minutes and may be categorized as a PA+++ UVA protective sunscreen product.

Table 1

Individual PFA Values

Subject	CPTC#	Skin Type	Age/ Sex	<u>Standard</u>		
				120 Min.	180 Min.	240 Min.
1) AR	26440	III	18/F	4.68	4.68	4.68
2) AV	26439	III	18/M	3.00	3.00	3.00
3) AE	22141	III	54/M	3.75	3.75	3.75
4) JP	24795	III	60/M	3.00	3.00	3.00
5) GD	24794	III	58/F	3.76	3.76	3.76
6) JC	16363	III	20/M	3.00	3.00	3.00
7) TC	9004	III	44/M	3.01	2.39	2.39
8) JP	14341	IV	51/F	3.00	3.00	3.00
9) AL	26661	III	33/M	3.01	2.99	2.99
10) SA	26539	III	59/F	4.69	3.75	3.75
11) DO	27187	III	29/F	3.75	2.99	2.99
Average PFA (N=11)				3.51	3.30	3.30
(95% Confidence Limits)				(3.06-3.96)	(2.88-3.72)	(2.88-3.72)
Standard Deviation				0.67	0.62	0.62
Standard Error				0.20	0.19	0.19
Subject	CPTC#	Skin Type	Age/ Sex	<u>Product A</u>		
				120 Min.	180 Min.	240 Min.
1) AR	26440	III	18/F	3.00	3.00	3.00
2) AV	26439	III	18/M	3.00	3.00	3.00
3) AE	22141	III	54/M	2.39	3.75	3.75
4) JP	24795	III	60/M	3.00	3.00	3.00
5) GD	24794	III	58/F	3.76	3.76	3.76
6) JC	16363	III	20/M	3.75	3.75	3.75
7) TC	9004	III	44/M	3.01	2.39	2.39
8) JP	14341	IV	51/F	3.00	3.00	3.00
9) AL	26661	III	33/M	3.00	3.00	3.00
10) SA	26539	III	59/F	2.99	2.39	2.39
11) DO	27187	III	29/F	4.69	3.75	>3.75*
Average PFA (N=11)				3.24	3.16	>3.16
(95% Confidence Limits)				(2.83-3.65)	(2.81-3.51)	
Standard Deviation				0.61	0.52	----
Standard Error				0.18	0.16	----

*calculated as actual value

Table 2

Individual PFA Values

Subject	CPTC#	Skin Type	Age/ Sex	<u>Standard</u>		
				120 Min.	180 Min.	240 Min.
1) AR	26440	III	18/F	4.68	4.68	4.68
2) AV	26439	III	18/M	3.00	3.00	3.00
3) AE	22141	III	54/M	3.75	3.75	3.75
4) JP	24795	III	60/M	3.00	3.00	3.00
5) GD	24794	III	58/F	3.76	3.76	3.76
6) JC	16363	III	20/M	3.00	3.00	3.00
7) TC	9004	III	44/M	3.01	2.39	2.39
8) JP	14341	IV	51/F	3.00	3.00	3.00
9) AL	26661	III	33/M	3.01	2.99	2.99
10) SA	26539	III	59/F	4.69	3.75	3.75
11) DO	27187	III	29/F	3.75	2.99	2.99
Average PFA (N=11)				3.51	3.30	3.30
(95% Confidence Limits)				(3.06-3.96)	(2.88-3.72)	(2.88-3.72)
Standard Deviation				0.67	0.62	0.62
Standard Error				0.20	0.19	0.19

Subject	CPTC#	Skin Type	Age/ Sex	<u>CTFA Sunscreen Sample E</u>		
				120 Min.	180 Min.	240 Min.
1) AR	26440	III	18/F	1.60	1.60	1.60
2) AV	26439	III	18/M	1.28	1.28	1.28
3) AE	22141	III	54/M	1.28	1.60	1.60
4) JP	24795	III	60/M	1.28	1.28	1.28
5) GD	24794	III	58/F	1.60	1.60	2.00
6) JC	16363	III	20/M	1.60	1.60	1.60
7) TC	9004	III	44/M	2.00	1.60	1.60
8) JP	14341	IV	51/F	2.00	2.00	2.00
9) AL	26661	III	33/M	1.60	1.28	1.28
10) SA	26539	III	59/F	1.60	1.28	1.28
11) DO	27187	III	29/F	3.13	2.50	2.50
Average PFA (N=11)				1.72	1.60	1.64
(95% Confidence Limits)				(1.36-2.08)	(1.35-1.85)	(1.38-1.90)
Standard Deviation				0.53	0.37	0.39
Standard Error				0.16	0.11	0.12

Table 3

Individual PFA Values

Subject	CPTC#	Skin Type	Age/ Sex	<u>Standard</u>		
				120 Min.	180 Min.	240 Min.
1) AR	26440	III	18/F	4.68	4.68	4.68
2) AV	26439	III	18/M	3.00	3.00	3.00
3) AE	22141	III	54/M	3.75	3.75	3.75
4) JP	24795	III	60/M	3.00	3.00	3.00
5) GD	24794	III	58/F	3.76	3.76	3.76
6) JC	16363	III	20/M	3.00	3.00	3.00
7) TC	9004	III	44/M	3.01	2.39	2.39
8) JP	14341	IV	51/F	3.00	3.00	3.00
9) AL	26661	III	33/M	3.01	2.99	2.99
10) SA	26539	III	59/F	4.69	3.75	3.75
11) DO	27187	III	29/F	3.75	2.99	2.99
Average PFA (N=11)				3.51	3.30	3.30
(95% Confidence Limits)				(3.06-3.96)	(2.88-3.72)	(2.88-3.72)
Standard Deviation				0.67	0.62	0.62
Standard Error				0.20	0.19	0.19

Subject	CPTC#	Skin Type	Age/ Sex	<u>CTFA Sunscreen Sample F</u>		
				120 Min.	180 Min.	240 Min.
1) AR	26440	III	18/F	3.75	4.69	4.69
2) AV	26439	III	18/M	3.00	3.00	3.00
3) AE	22141	III	54/M	2.39	2.39	2.39
4) JP	24795	III	60/M	3.00	3.00	3.00
5) GD	24794	III	58/F	3.76	3.76	3.76
6) JC	16363	III	20/M	3.00	3.00	3.00
7) TC	9004	III	44/M	3.01	2.39	2.39
8) JP	14341	IV	51/F	2.40	2.40	2.40
9) AL	26661	III	33/M	3.75	3.00	3.00
10) SA	26539	III	59/F	3.75	2.99	2.99
11) DO	27187	III	29/F	3.75	2.99	2.99
Average PFA (N=11)				3.23	3.06	3.06
(95% Confidence Limits)				(2.86-3.60)	(2.61-3.51)	(2.61-3.51)
Standard Deviation				0.54	0.67	0.67
Standard Error				0.16	0.20	0.20

Table 4

Individual PFA Values

Subject	CPTC#	Skin Type	Age/ Sex	<u>Standard</u>		
				120 Min.	180 Min.	240 Min.
JL	10041	IV	44/M	3.00	3.00	3.00
PM	25156	III	53/F	3.01	3.01	3.01
WM	25157	III	51/M	3.75	2.99	2.99
RR	19018	III	44/M	3.75	3.75	3.75
FA	25124	III	28/M	3.01	3.01	3.01
AM	19625	IV	38/M	3.01	3.01	3.01
CD	25644	III	19/F	3.00	3.00	3.00
NF	18802	III	57/F	4.70	4.70	4.70
NC	12798	III	53/F	3.75	3.75	3.75
MP	26044	III	25/M	3.00	3.00	3.00
Average PFA (N=10)				3.40	3.32	3.32
(95% Confidence Limits)				(2.99-3.81)	(2.91-3.73)	(2.91-3.73)
Standard Deviation				0.58	0.58	0.58
Standard Error				0.18	0.18	0.18

Subject	CPTC#	Skin Type	Age/ Sex	<u>CTFA Sunscreen Sample G</u>		
				120 Min.	180 Min.	240 Min.
JL	10041	IV	44/M	3.20	4.00	4.00
PM	25156	III	53/F	3.20	3.20	3.20
WM	25157	III	51/M	4.00	3.20	3.20
RR	19018	III	44/M	5.00	3.99	3.99
FA	25124	III	28/M	5.00	5.00	5.00
AM	19625	IV	38/M	3.20	3.20	3.20
CD	25644	III	19/F	4.00	4.00	4.00
NF	18802	III	57/F	3.21	3.21	4.01
NC	12798	III	53/F	4.00	4.00	4.00
MP	26044	III	25/M	4.00	4.00	4.00
Average PFA (N=10)				3.88	3.78	3.86
(95% Confidence Limits)				(3.38-4.38)	(3.36-4.20)	(3.47-4.25)
Standard Deviation				0.70	0.58	0.55
Standard Error				0.22	0.18	0.17

Table 5

Individual PFA Values

Subject	CPTC#	Skin Type	Age/ Sex	<u>Standard</u>		
				120 Min.	180 Min.	240 Min.
JL	10041	IV	44/M	3.00	3.00	3.00
PM	25156	III	53/F	3.01	3.01	3.01
WM	25157	III	51/M	3.75	2.99	2.99
RR	19018	III	44/M	3.75	3.75	3.75
FA	25124	III	28/M	3.01	3.01	3.01
AM	19625	IV	38/M	3.01	3.01	3.01
CD	25644	III	19/F	3.00	3.00	3.00
NF	18802	III	57/F	4.70	4.70	4.70
NC	12798	III	53/F	3.75	3.75	3.75
MP	26044	III	25/M	3.00	3.00	3.00
Average PFA (N=10)				3.40	3.32	3.32
(95% Confidence Limits)				(2.99-3.81)	(2.91-3.73)	(2.91-3.73)
Standard Deviation				0.58	0.58	0.58
Standard Error				0.18	0.18	0.18
Subject	CPTC#	Skin Type	Age/ Sex	<u>CTFA Sunscreen Sample H</u>		
				120 Min.	180 Min.	240 Min.
JL	10041	IV	44/M	5.00	6.25	6.25
PM	25156	III	53/F	3.20	4.00	4.00
WM	25157	III	51/M	5.00	2.56	2.56
RR	19018	III	44/M	4.00	3.20	3.20
FA	25124	III	28/M	5.00	6.25	6.25
AM	19625	IV	38/M	3.20	4.00	4.00
CD	25644	III	19/F	4.00	5.00	5.00
NF	18802	III	57/F	3.21	3.21	4.01
NC	12798	III	53/F	3.20	5.00	5.00
MP	26044	III	25/M	4.00	4.00	4.00
Average PFA (N=10)				3.98	4.35	4.43
(95% Confidence Limits)				(3.42-4.54)	(3.45-5.25)	(3.57-5.29)
Standard Deviation				0.78	1.26	1.20
Standard Error				0.25	0.40	0.38

Table 6

Individual PFA Values

Subject	CPTC#	Skin Type	Age/ Sex	<u>Standard</u>		
				120 Min.	180 Min.	240 Min.
JL	10041	IV	44/M	3.00	3.00	3.00
PM	25156	III	53/F	3.01	3.01	3.01
WM	25157	III	51/M	3.75	2.99	2.99
RR	19018	III	44/M	3.75	3.75	3.75
FA	25124	III	28/M	3.01	3.01	3.01
AM	19625	IV	38/M	3.01	3.01	3.01
CD	25644	III	19/F	3.00	3.00	3.00
NF	18802	III	57/F	4.70	4.70	4.70
NC	12798	III	53/F	3.75	3.75	3.75
MP	26044	III	25/M	3.00	3.00	3.00
Average PFA (N=10)				3.40	3.32	3.32
(95% Confidence Limits)				(2.99-3.81)	(2.91-3.73)	(2.91-3.73)
Standard Deviation				0.58	0.58	0.58
Standard Error				0.18	0.18	0.18
Subject	CPTC#	Skin Type	Age/ Sex	<u>CTFA Sunscreen Sample I</u>		
				120 Min.	180 Min.	240 Min.
JL	10041	IV	44/M	2.00	2.00	2.00
PM	25156	III	53/F	2.50	2.50	2.50
WM	25157	III	51/M	2.00	1.99	1.99
RR	19018	III	44/M	2.50	2.00	2.00
FA	25124	III	28/M	2.00	2.50	2.50
AM	19625	IV	38/M	3.13	3.13	3.13
CD	25644	III	19/F	2.50	2.50	2.50
NF	18802	III	57/F	2.51	2.51	2.51
NC	12798	III	53/F	2.00	2.00	2.00
MP	26044	III	25/M	1.60	1.60	2.00
Average PFA (N=10)				2.27	2.27	2.31
(95% Confidence Limits)				(1.96-2.58)	(1.96-2.58)	(2.04-2.58)
Standard Deviation				0.43	0.43	0.38
Standard Error				0.14	0.14	0.12

Table 7

Individual PFA Values

Subject	CPTC#	Skin Type	Age/ Sex	<u>Standard</u>		
				120 Min.	180 Min.	240 Min.
1) RP	3261	III	45/F	3.75	3.75	3.75
2) EC	14383	III	55/F	3.75	3.75	3.75
3) GA	10123	IV	39/F	3.75	4.69	4.69
4) LA	19406	IV	45/M	3.00	3.00	3.00
5) NC	23001	III	21/F	3.75	3.75	3.75
6) AA	27074	III	28/F	3.75	3.75	3.75
7) EP	5819	III	59/F	4.70	4.70	4.70
8) SZ	10865	IV	27/F	3.00	3.00	3.00
9) RH	600	III	53/F	4.68	4.68	4.68
10) JY	12714	III	48/F	3.75	4.69	3.73
Average PFA (N=10)				3.79	3.98	3.88
(95% Confidence Limits)				(3.39-4.19)	(3.49-4.47)	(3.43-4.33)
Standard Deviation				0.57	0.68	0.63
Standard Error				0.18	0.21	0.20
Subject	CPTC#	Skin Type	Age/ Sex	<u>CTFA Sunscreen Sample J</u>		
				120 Min.	180 Min.	240 Min.
1) RP	3261	III	45/F	11.25	11.25	11.25
2) EC	14383	III	55/F	11.24	11.24	11.24
3) GA	10123	IV	39/F	11.24	11.24	11.24
4) LA	19406	IV	45/M	9.00	9.00	9.00
5) NC	23001	III	21/F	11.25	11.25	11.25
6) AA	27074	III	28/F	11.25	11.25	11.25
7) EP	5819	III	59/F	11.28	11.28	11.28
8) SZ	10865	IV	27/F	9.00	9.00	9.00
9) RH	600	III	53/F	11.24	11.24	11.24
10) JY	12714	III	48/F	11.26	11.26	8.95
Average PFA (N=10)				10.80	10.80	10.57
(95% Confidence Limits)				(10.12-11.48)	(10.12-11.48)	(9.79-11.35)
Standard Deviation				0.95	0.95	1.10
Standard Error				0.30	0.30	0.35

PPD DATA SUMMARY FROM TKL RESEARCH



SUMMARY REPORT

TKL Study No. PB840300

Date of Report 5/23/2000

Title:	Determination of UVA Induced Minimal Persistent Pigment Darkening (MPPD) For Determination of UVA-Protection Factors.	
TKL Protocol No.:	TKL-8401-M	
Objective:	To determine the UVA-Protection factor of a sunscreen product.	
Design of Study:	UVA induced Persistent Pigment Darkening methodology as set forth in the Japan Cosmetic Industry Association's "Measurement Standards for UVA Protection Efficacy". Product application and UVA irradiation followed by a two-hour evaluation to determine UVA-PF values.	
Principal Investigator:	Alan H. Greenspan, MD	
Clinical Research Coordinator:	Maureen Damstra, BA, CCRC	
Study Sponsor:	THE COSMETIC, TOILETRY, AND FRAGRANCE ASSOCIATION 1101 17 th St. NW, Suite 300 Washington, DC 20036-4702 Attention: Gerald McEwen, Ph.D	
Study Center:	TKL Research, Inc. 4 Forest Avenue Paramus, NJ 07652	
Study Dates:	Date Initiated:	February 23, 2000
	Date Completed:	April 7, 2000
Study Products:	<u>CTFA Sample # / Product ID</u>	
	A: White lotion	H: White Cream
	E: White lotion	I: White lotion
	F: White lotion	J: White lotion
	G: White lotion	
Number of Subjects:	Enrolled: <u>28</u>	Completed: <u>28</u>

SUMMARY REPORT (Cont'd)
TKL Study No. PB840300
CTFA

Listing of Attached Tables:

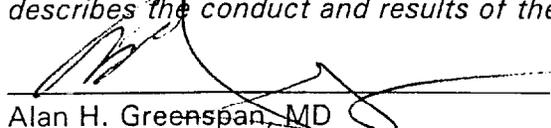
Appendix I UVA-Protection factors (PFA) Result Tables
 Appendix II Fitzpatrick Skin Type Table
 Appendix III Study Demographics

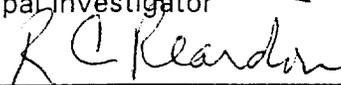
Summary - Conclusions: The following UVA-Protection factors (PFA) and associated values were obtained following UVA Persistent Pigment Darkening Response Methodology:

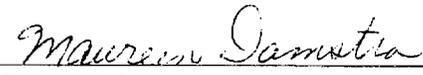
PRODUCT NUMBER	EST. PFA	UVA-PFA/STD. DEVIATION	STANDARD ERROR	10% OF MEAN	COMMENTS
A	2-4	3.18±0.85 N = 10	0.27	0.32	No unacceptable results
E	1-3	1.58±0.26 N = 10	0.08	0.16	No unacceptable results
F	2-4	2.95±0.70 N = 10	0.22	0.30	One subject's (Entry No. 02) results were rejected due to lack of protection at irradiated sub-sites
G	3-5	4.65±1.62 N = 13	0.45	0.47	No unacceptable results
H	3-5	3.43±0.81 N = 10	0.26	0.34	No unacceptable results
I	1-3	2.18±0.49 N = 11	0.15	0.22	No unacceptable results
J	9-11	14.07±4.05 N = 11	1.22	1.41	No unacceptable results
Standard Control	4	4.27±0.83 N = 28	0.16	0.43	No unacceptable results

Signatures:

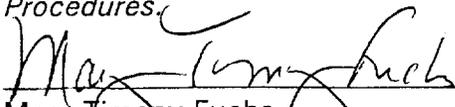
I have read this report and confirm that to the best of my knowledge it accurately describes the conduct and results of the study.

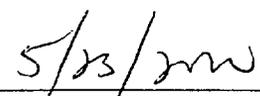

 Alan H. Greenspan, MD
 Principal Investigator


 Robert C. Reardon, PhD
 Director of Operations


 Maureen Damstra, BA, CCRC,
 Clinical Research Coordinator and
 Manager, Photobiology

All data and supporting documentation for this study and report have been audited by the TKL Quality Assurance Department and found to be accurate and complete and in compliance with all requirements of the protocol and TKL's Standard Operating Procedures.


 Mary Timony-Fuchs
 Senior Quality Assurance


 Date

APPENDIX I

UVA-PROTECTION FACTORS (PFA) RESULT TABLES

Table 1

<u>Subject Number</u>	Product No. <u>"A"</u>
02	3.75
04	3.75
05	3.75
07	3.00
08	1.92
11	1.92
12	3.00
13	3.00
15	4.69
17	3.00
Mean=	3.18
SD=	0.85
SE=	0.27
10% MEAN=	0.32
N=10	

Table 2

<u>Subject Number</u>	Product No. <u>"E"</u>
01	1.28
05	1.28
06	2.00
07	1.60
08	2.00
13	1.60
14	1.60
18	1.60
19	1.60
20	1.28
Mean=	1.58
SD=	0.26
SE=	0.08
10% MEAN=	0.16
N=10	

Table 3

<u>Subject Number</u>	Product No. <u>"F"</u>
04	2.40
05	3.75
06	3.75
09	3.00
10	3.00
14	3.00
16	1.92
17	3.00
18	1.92
19	3.75
Mean=	2.95
SD=	0.70
SE=	0.22
10% MEAN=	0.30
N=10	

Table 4

<u>Subject Number</u>	Product No. <u>"G"</u>
01	5.00
02	7.82
03	4.00
04	4.00
09	3.20
10	4.00
11	3.20
12	6.26
15	7.82
16	3.20
20	4.00
22	4.00
23	4.00
Mean=	4.65
SD=	1.62
SE=	0.45
10% MEAN=	0.47
N=13	

Table 5

<u>Subject Number</u>	Product No. <u>"H"</u>
01	5.00
03	2.56
06	4.00
07	2.56
08	3.20
09	3.20
10	4.00
11	4.00
12	5.00
13	3.20
14	2.56
Mean=	3.57
SD=	0.90
SE=	0.27
10% MEAN=	0.36
N=11	

Table 6

<u>Subject Number</u>	<u>Product No.</u>
15	3.13
16	2.00
17	2.00
18	1.60
19	2.50
20	2.50
21	2.00
22	1.60
23	1.60
24	2.50
25	2.50
Mean=	2.18
SD=	0.49
SE=	0.15
10% MEAN=	0.22
N=11	

Table 7

<u>Subject Number</u>	<u>Product No.</u> <u>"J"</u>
24	16.27
25	10.40
12	15.64
15	11.00
23	13.77
17	21.51
07	17.21
26	11.00
27	7.03
28	13.75
18	17.19
Mean=	14.07
SD=	4.05
SE=	1.22
10% MEAN=	1.41
N=11	

<u>Subject Number</u>	<u>Product No. STANDARD CONTROL</u>
01	6.26
02	5.00
03	3.20
04	4.00
05	4.00
06	4.00
07	3.20
08	4.00
09	4.00
10	5.00
11	3.20
12	5.00
13	5.00
14	5.00
15	5.00
16	3.20
17	5.00
18	4.00
19	4.00
20	5.00
21	3.20
22	3.20
23	5.00
24	5.00
25	4.00
26	5.01
27	3.20
28	4.00

Mean= 4.27

SD= 0.83

SE= 0.16

10% MEAN= 0.43

N=

28

107

APPENDIX II

FITZPATRICK SKIN TYPE TABLE

Entry No.	SKIN TYPE
01	III
02	III
03	IV
04	III
05	III
06	III
07	IV
08	IV
09	IV
10	III
11	IV
12	IV
13	III
14	III
15	IV
16	III
17	IV
18	III
19	III
20	III
21	III
22	III
23	IV
24	III
25	III
26	III
27	IV
28	IV

Key:

III. Burns moderately; tans gradually

IV. Burns minimally; always tans well

APPENDIX III

STUDY DEMOGRAPHICS

KEY:

F = Female

M = Male

DEMOGRAPHICS

Entry No.	Subject No.	Sex	Race	Age
01	58366	F	HISPANIC	39
02	47587	F	WHITE	54
03	66668	F	WHITE	26
04	15784	F	WHITE	40
05	54051	F	WHITE	43
06	19735	F	WHITE	43
07	50253	M	ASIAN	27
08	62363	F	HISPANIC	28
09	55625	M	HISPANIC	35
10	50518	F	HISPANIC	24
11	52858	F	ASIAN	24
12	48256	M	HISPANIC	23
13	61911	F	HISPANIC	42
14	49460	F	HISPANIC	45
15	63111	F	ASIAN	59
16	63749	F	HISPANIC	32
17	47484	F	ASIAN	25
18	59996	F	HISPANIC	49
19	45220	F	WHITE	45
20	66375	F	WHITE	40
21	61695	M	HISPANIC	62
22	62495	F	HISPANIC	54
23	66883	F	HISPANIC	35
24	16055	F	WHITE	60
25	66551	F	WHITE	42
26	61261	F	HISPANIC	42
27	62000	F	ASIAN	32
28	63695	F	ASIAN	43

DISTRIBUTION OF AGES

Under 18	: n =	0
18 to 25	: n =	4
26 to 35	: n =	7
36 to 45	: n =	11
46 to 55	: n =	3
56 to 65	: n =	3
Over 65	: n =	0
Total	: n =	28

Mean Age: 39.8

Median Age: 41

Age range for the study: 23 to 62